



9205 '99 DEC 21 P2:03

December 9, 1999

Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fisher Lane, Room 1061
Rockville, MD 20852

RE: FDA Proposal to Regulate Allograft Tissue
DOCKET #: 97N-484S

To Whom It May Concern:

As a practicing orthopedic spine surgeon, I would like to place my comments on the record regarding the FDA's proposal to regulate allograft tissue as a medical device.

I would strongly oppose such regulation. I use allograft bone tissue on a regular basis in my practice and have done so for the past six years. Allograft material is useful to us on a daily basis for the treatment of patients with multiple orthopedic problems. This tissue has been used throughout the history of orthopedics and has not required regulatory supervision other than the excellent quality control measures which are already in place by most practicing tissue banks. As the history of orthopedics has shown, the utilization of allograft bone is safe and has a longstanding track record. It is not a new implantable medical device requiring FDA supervision.

If these bone tissues were to fall under the typical regulatory processes, it would grind many of the standard and acceptable orthopedic practices to a halt. This would place the majority of my patient's at a severe disadvantage, requiring me to harvest allograft bone in selected situations where we have had excellent results with allograft. Additionally, some of our allograft requirements are so extensive and so structural, we cannot adequately find substitute tissue within the patient's own body. These patients, therefore, would not have a treatment option which they have currently enjoyed for the past twenty years without issue.

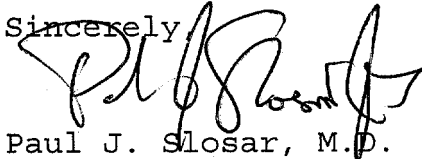
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I strongly urge the FDA to not regulate allograft bone tissue as a medical device.

Sincerely,

A handwritten signature in black ink, appearing to read "Paul J. Slosar", written over the word "Sincerely,".

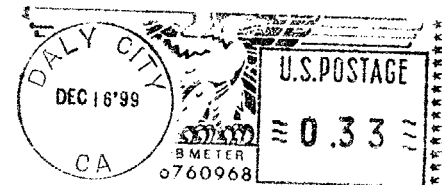
Paul J. Slosar, M.D.

PJS:tmj



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